

### **Remarks**

The following is a response to the Office Action dated December 27, 2005.

In response to the objection to the Abstract, being submitted is a substitute Abstract which does not exceed the 150 word limit.

Claims 1-4, 6-8, 14-16, 23 and 25-26 were rejected under 35 U.S.C. 102(b) as being anticipated by Gyure et al. (US 5,665,075). Claims 5, 11-12, 17-21, 24 and 28 were rejected under 35 U.S.C. 103 as being obvious over Gyure in combination with the Landis (US 5,490,841). Claims 9-10 and 13 were rejected under 35 U.S.C. 103 as being obvious over Gyure in combination with Hollister (US 6,328,713).

The instant invention, with respect to independent claims 1, 14, 17 and 23, in one way or the other, relates to the connection of a needle sheath to the collar that is rotatably mounted about a needle hub. Additional attributes for defining such coupling of the needle sheath to a collar prior to use is given in the noted independent claims.

Prior to the instant invention, needle sheaths are coupled to the needle hub prior to use for protecting the needle that extends from the needle hub.

Gyure '075 is no exception. As shown in Fig. 2, the needle hub 28 of the Gyure '075 device has formed thereat a collar receiving recess 34. A needle cover or sheath 37 is fitted to the needle hub 28. To enhance the examiner's understanding of the coupling of sheath 37 to needle hub 28, attached is a Fig. 2 Appendix with designation A, showing the space formed by collar receiving recess 34 about the distal portion of needle hub 28, to which the portion B of sheath 37, as designated in the Appendix, is fitted. This fitting of sheath 37 to needle hub 28 is disclosed in column 4, lines 27-31 which state: "An elongate rigid needle cover 37 having a cylindrically-shaped sidewall 38 and an open proximal end 39 removably engages hub 28 and covers needle cannula 21, as best illustrated in Fig. 2."

Thus, it is clear that the needle sheath 37 is coupled to needle hub 28, and not to collar 34 as shown in Fig. 2. As further disclosed in column 3, lines 50-65, and more particularly disclosed in column 5, lines 47-56, once needle sheath 37 is fitted to needle hub 28, with the identified B portion of sheath 37 fitted to the identified A portion of needle hub 28, the circumferential flange 40 is positioned adjacent to the raised portion 33 of the needle hub, so that collar 44 can be slidably passed along sheath 37, and be guided by flange 40 into the collar receiving recess 34. Thus, there is no teaching, or suggestion, in Gyure '075 of a needle sheath being removably attached to the collar prior to use. Quite the contrary, Gyure '075, as noted above per the quoted passage, specifically discloses that its needle sheath 37 is coupled to the needle hub 28. That being the case, it is respectfully submitted that independent claims 1, 14, 17 and 23, as well as the claims respectively dependant therefrom, are not anticipated by Gyure '075.

Nor could those claims be obvious over the combination of Gyure and Landis, as Landis fails to teach a needle protective housing that has two lips that are angled toward the interior of the housing with the respective angles of each of the lips being varied along the length of the housing, as illustrated for example in Figs. 4, 5 and 6 of the instant application. Landis shows, per his Figs. 7a-7e and Fig. 8, a trap door 20. In his Figs. 9a, 9b and 11, Landis does show two trap doors. However, nowhere in Landis is there any disclosure that these trap doors are progressively angled toward the interior of the housing, with the angles of each of the lips being varied along the length of the housing, as required in claim 11. Moreover, as mentioned above, there is no disclosure in Gyure '075 of any collar having a retainer at its inner surface for removably retaining a needle sheath prior to use, as require in claim 17.

Additional comments in the Office Action that deem to require response include the following.

What is deemed to be a spline (40) by the examiner in claim 4 is actually a circumferential flange, as noted above. Such flange 40 in the Gyure device has no bearing

whatsoever with respect to the limitations recited in claim 4. Nor is there anything disclosed in Gyure that would meet the limitations recited in claim 6 or those in claim 8. Likewise, there is nothing in the prior art that, either singly or in combination, would meet the limitations recited in claims 12, 14, 15, 18, 19, 20, 21, or the method claims of 23-28.

In light of the above, the examiner is respectfully requested to reconsider the application and pass the case to issue at an early date.

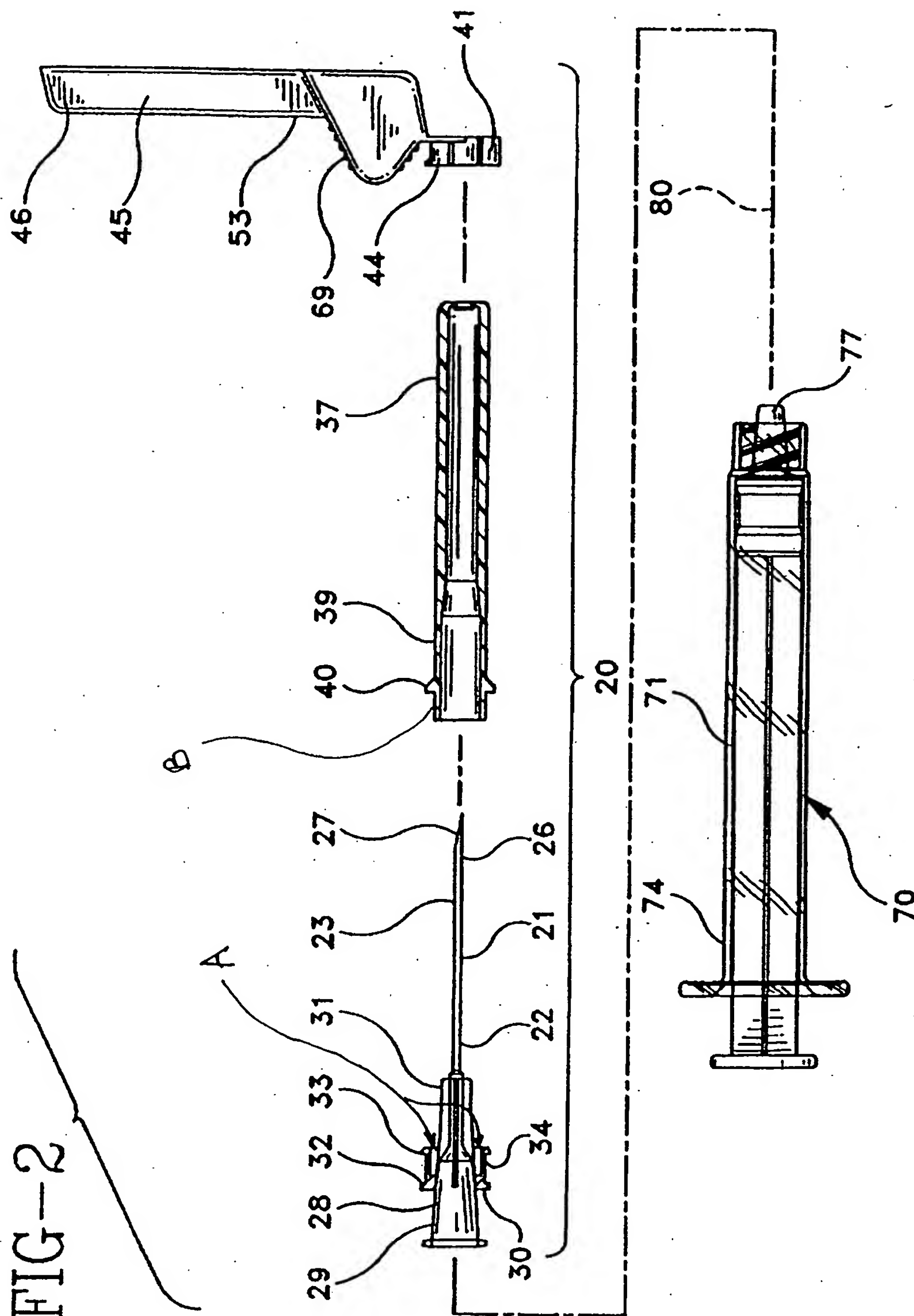
Respectfully submitted,



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## Appendix